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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,613	06/27/2001	Shawn Shui-on Leung	655	4914

7590

06/04/2003

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EXAMINER

HELMS, LARRY RONALD

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/04/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,613

Applicant(s)

LEUNG, SHAWN SHUI-ON

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 2, 4-13 have been amended.
2. Claims 14-15, 20-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 14.
3. Claims 1-13 and 16-19 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Rejections Withdrawn

5. The rejection of claims 1-13 under 35 U.S.C. 112, second paragraph, for parts (a), (e), and (f) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of arguments.
6. The rejection of claims 1-13 and 19 under 35 U.S.C. 112, first paragraph is withdrawn in view of arguments.

Response to Arguments

7. The rejection of claims 1-13 under 35 U.S.C. 112, second paragraph, for parts (b), (c), (d), (g)-(i) in the last office action, as being indefinite for failing to particularly

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point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

The response filed 4/7/03 has been carefully considered but is deemed not to be persuasive. The response states that "affinity comparable to" means within 10 fold (see page 7). In response to this argument, the claim should recite this limitation if the phrase means it.

The response further states that "said re-engineered immunoglobulin chain" refers to a chain re-engineered. And different immunoglobulin chain is recited before as at least two different sources of immunoglobulin chains (see page 7). There is still insufficient antecedent basis for this limitation in the claim.

The response further states that it is well understood what the meaning of conservatively similar is. In response to this the rejection did not have any thing to do with this . The rejection was for the phrase "such as". See MPEP § 2173.05(d).

The response further states that "preferably 100%" means that it is identical. In response to this argument, then this limitation should be in the claim because it is not clear if the sequence homology is to be 100%.

The response further states that the phrase "back mutated amino acids" refers to reintroduced from the parent. In response to this the claim should indicate this language for the definition of the phrase.

8. The rejection of claims 16-19 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is maintained.

The response filed 4/7/03 has been carefully considered but is deemed not to be persuasive. The response states that the conversion of amino acids to DNA requires only textbook knowledge and the invention only requires routine procedures and both RFB4 and 1F5 are commercially available and the FR-patched antibodies are described in the application (see pages 9-10 of response). In response to this argument, while it may be routine to perform the methods, the antibodies of RFB4 and 1F5 are needed to practice the invention and the response does not provide adequate demonstration that the hybridomas that produce the antibodies of RFB4 and 1F5 are commercially available.

9. The rejection of claims 1-13 under 35 U.S.C. 102(b) as being anticipated by Queen et al (U.S. Patent 5,693,762, issued 12/97, IDS #1 ½) is maintained.

The response filed 4/7/03 has been carefully considered but is deemed not to be persuasive. The response states that Queen et al uses the whole set of framework sequences from one single antibody for CDR grafting (see page 14-15) and the present invention is not confined to a single source for the framework regions (see page 16) and

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Queen et al will not suggest or make obvious to partition frameworks into independent segments (see page 17 of response) and the current method keeps back mutations to a minimum (see page 19) and homology of Queen is for the entire framework not a compartmentalized FR (see page 20). In response to these arguments, the claims do not require each FR to be separated into independent segments and the homology based on a separate FR. Queen et al teach a framework that is most homologous and back mutations. While it is asserted that the present invention tries to avoid back mutations, the claims require it and Queen et al teach such.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER